

Appl. No. : 09/892,900
Filed : June 26, 2001

AMENDMENTS TO THE SPECIFICATION

Please amend the title of the application as follows:

PN2
10-16-03

~~FLUID CONTAINER FOR USE WITH PLATEN PUMP~~
A

Please amend the first paragraph of the specification as follows:

N.E.
This application is a ~~continuation~~ divisional of copending application Serial No. 876,180 filed June 23, 1997, now U.S. Patent No. 6,251,098 issued June 26, 2001, which is a continuation of Application No. 08/763,875, filed December 11, 1996, abandoned, which is a continuation of Application No. 08/385,083, filed February 7, 1995, abandoned, which is a continuation of Application No. 08/008,790, filed January 22, 1993, abandoned, which is a continuation-in-part of copending application Serial No. 898,958 filed June 15, 1992, abandoned, which is a continuation-in-part of copending application Serial No. 824,855 filed January 24, 1992, now U.S. Patent No. 5,911,716 issued June 15, 1999.

Please amend the paragraph beginning at page 1, line 7 as follows:

B2
This invention relates to a ~~low cost fluid container for use with~~ a drug delivery system, and, more particularly, to a fluid pump configured to deliver fluid at a relatively constant flow rate.

Please replace the paragraph beginning at page 2, line 31 with the following new paragraph:

N.E.
A preferred embodiment of the present invention involves an infusion pump including a first shell defining a non-planar interior surface and a second shell removably secured to the first shell. A platen defines a non-planar surface complementary to the interior surface of the first shell and is positioned between the first and second shells such that the non-planar surface of the platen faces the interior surface of the first shell. The non-planar surface of the platen and the non-planar surface of the first shell define a variable-volume space therebetween. The variable-volume space is configured to hold a fluid delivery bag therein. The fluid delivery bag may be constructed from a variety of materials and may be of a variety of suitable shapes. A biasing member, such as a spring, is arranged to bias the platen in a first direction to decrease the volume of the space wherein the spring, the platen and the interior surface are configured to compress the fluid delivery bag to expel fluid therefrom when the platen is moving in the first direction.

Please amend the paragraph beginning at page 3, line 32 as follows:

B4 Figures 5a and 5b are a plan view and side view, respectively, of the rotatable spring retainer used in the infusion ~~devices~~ device of Figure 1.

Please amend the paragraph beginning at page 4, line 8 as follows:

B5 Figure 8a is a partial cross-sectional view of the infusion device of Figure 8 in an open position.

Please amend the paragraph beginning at page 4, line 10 as follows:

B6 Figure 8b is a partial cross-sectional view of the infusion device of Figure 8 in a closed position.

Please amend the paragraph beginning at page 4, line 15 as follows:

B7 Figure 10 is an elevational cross-sectional view of the pump illustrated in Figure 9, taken along a vertical plane passing through line 10-10 of Figure 9.

Please amend the paragraph beginning at page 6, line 12 as follows:

B8 Figure 35 is a ~~top plan~~ cross-sectional view of the embodiment illustrated in Figure 34, taken along line 35-35 of Figure 34.

Please amend the paragraph beginning at page 6, line 14 as follows:

B9 Figure 36 is a ~~top plan~~ cross-sectional view of a flexible platen retraction device in accordance with the present invention.

Please amend the paragraph beginning at page 6, line 29 as follows:

B10 Figure 42 is ~~an elevational~~ a cross-sectional view of a linkage assembly.

Please amend the paragraph beginning at page 6, line 30 as follows:

B11 Figure 43 is ~~an elevational~~ a cross-sectional view of an alternate linkage assembly.

Please amend the paragraph beginning at page 7, line 19 as follows:

B12 Figure 53 is an elevational cross-sectional view of the embodiment of Figure 52 taken along a vertical plane passing through line 53-53 of Figure 52.

Please amend the paragraph beginning at page 16, line 30 as follows:

B13 Referring now to Figures 8, 8a and 8b, an alternate embodiment of the present invention illustrated. ~~The numerical labels in the drawings are 100 higher than corresponding similar elements in the first embodiment.~~ When it is desired to use a conventional rectangular drug delivery bag ~~108~~ ¹¹⁸, the alternate embodiment can be used. The fluid containing shell 116 of the alternate embodiment is provided with a rectangular chamber to accommodate the rectangular

Appl. No. : 09/892,900
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CONT
drug delivery bag. The fluid containing shell 116 is formed by an upper portion 152 and lower portion 154 attached at one end by a hinge 156. The opposite ends are connected by a latch 158 when the upper and lower portions are closed. The upper portion 152 includes a threaded cylindrical wall 119 for interfacing with the threaded wall 113 of the pressurizing shell 112. The platen 124 attached to the spring 114 of the pressurizing shell 112 is made rectangular to fit over the substantially flat center portion of the rectangular bag.

Please amend the paragraph beginning at page 31, line 23 as follows:

B14
Also illustrated in Figure 30 is an alternative crank arrangement for retracting the platen 277. Crank 286 is pivotally attached to threaded shaft 280, so that it can be conveniently moved from a first compact position 287 such as during storage or use, to a second ready position 288, shown in phantom, in which the crank is positioned for use in retracting the platen 277.

Please amend the paragraph beginning at page 32, line 26 as follows:

B15
Threaded post 290 can be rotated using any of a variety of implements, such as an ~~allen wrench~~ ALLEN WRENCH or similar multi-sided tool, a crank, a rotatable nut, an electric drill, or others as will be apparent to one of skill in the art.

Please amend the paragraph beginning at page 34, line 1 as follows:

B16
In a preferred embodiment, two or more pneumatic cylinders 296 are provided. Thus, for example, there is disclosed in Figure 35 a ~~top plan~~ cross-sectional view of an infusion pump having seven pneumatic cylinders 296 positioned about the periphery of a medication bag. To facilitate retraction of the platen by infusing pressurized fluid or gas through only a single port 303, each of the chambers 299 of the pneumatic cylinders 296 are in communication with each other by way of a flow path 304.

Please amend the paragraph beginning at page 34, line 22 as follows:

B17
Alternatively, referring to Figures 36-38, there is disclosed a pneumatic retraction embodiment in which one or more flexible bladders are utilized to provide the force necessary to retract the platen against the spring bias. Thus, referring to Figure 36, there is disclosed a ~~top plan~~ cross-sectional view of an embodiment of the present invention having two elongate tubular bladders 306 in communication with a fill port 308 by way of lumen 307. As illustrated in Figures 37 and 38, inflation of the bladders 306 advances the platen against the spring bias provided by one or more springs 309 to provide sufficient space between platen 310 and base 311 to accommodate a full medication bag 312.

Please amend the paragraph beginning at page 39, line 25 as follows:

B18 Thus, referring to Figure 44, there is disclosed an infusion pump 334 having one or more springs 336 for biasing a platen 338 against a medication bag 340. Platen 338 is provided with at least one drag element 342 for contacting a friction element 342 344 throughout at least a portion of its axial length of travel. Drag element 342 can be provided in any of a variety of forms, and can extend radially outwardly within the plane of the platen 338, or be spaced apart axially from the plane of the platen, such as is illustrated in Figure 44.

Please amend the paragraph beginning at page 44, line 31 as follows:

B19 The lower limit on the range of ~~angles~~ angles between the path of travel of lever 374 and plane of platen 366 is governed by several factors. The axial component of the path of travel must be sufficient to fully retract the platen 366 so that a medication bag 368 can be inserted. Thus, as the angle decreases beyond a certain limit, the length of the path of travel must be increased to obtain the same axial component, thereby requiring a larger outer peripheral dimension of the device. In one preferred embodiment, the housing 362 has a length of about 5 inches and a thickness along the longitudinal axis of spring 364 of about 0.9 inches. Slot 370 inclines at an angle of about 15° from the plane of the central region of the platen 366, and has a length of about 2.2 inches.

Please amend the paragraph beginning at page 46, line 3 as follows:

B20 In general, base 404, annular wall 442, annular wall 444 and cover 402 cooperate to form a chamber 446 for containing the functional components of the infusion device. In the illustrated embodiment, a platen ~~segment~~ 410 is biased against a reservoir such as a flexible medication bag 406 by means of a spring and linkage assembly 411.

Please amend the paragraph beginning at page 50, line 4 as follows:

B21 Each block 420 and 420' may comprise any of a variety of durable materials such as aluminum, stainless steel or other metal known in the medical device arts. Preferably, however, a strong lightweight plastic material such as ~~Delrin~~ DELIN, available from DuPont is used. Polymeric blocks or coatings are preferred, due to their ability to slide relatively freely on the spring guide 414 when biased by the springs 412 and 412'.

Please amend the paragraph beginning at page 50, line 17 as follows:

B22 Two link arms 424 and 426 are pivotably affixed to each one pivot 438 at a first end thereof. Link arm 424 is connected at a second end to an anchor pivot 436 which is connected to

B22
CONT

the cover 402. Link arm 426 is connected at its second end to a platen pivot 434 which is connected to the platen 410. Link arms 424 and 426 form a scissor-type configuration which is a mirror image of the configuration of link arms 428 and 430. Together, the four link arms 424, 426, 428 and 430 form an adjustable parallelogram linkage, as will be understood by one of skill in the art. Preferably, an identical parallelogram linkage exists on the opposing vertical wall of blocks 420 and 420', as shown in Figure 55.

Please amend the paragraph beginning at page 52, line 12 as follows:

B23

A platen was constructed in accordance with the embodiment illustrated in Figures 52-55, having springs 412 and 412' comprised of music wire having a wire diameter of approximately .085 inch. Springs 412 and 412' had an outside diameter of about 0.5 inches, a spring constant of approximately 111 lbs. per inch, and were approximately 1.7 inches long in the uncompressed state and approximately 0.9 inch long in the fully compressed state, as shown in Figure 54. The sum of the axial travel of springs 412 and 412' was approximately 0.7 inch between the compressed state as shown in Figure 53 at the beginning of the dispensation cycle and the state shown in Figure 54 at the end of the dispensation cycle. The springs were preloaded to about 35 lbs. on each side, and were measured to generate a total spring force of about 160 lbs. Blocks 420 and 420' were constructed from ~~Delrin~~ DELIN, available from DuPont. The length of each of the four link arms was about 0.8 inches from pivot to pivot. The platen and opposing wall were substantially flat to isolate the pressure effects due to the spring biasing assembly.

Please amend the paragraph beginning at page 54, line 25 as follows:

B24

Referring to Figures 61-65, a fluid container 500 is provided which may be readily used with any of the previously disclosed embodiments of the platen pump. Preferably, the fluid container 500 consists of a collapsible medication reservoir or bag 510 in fluid communication with an effluent fluid line 530. The effluent fluid line 530 may lead to an administration set 540 shown in phantom in Figure 61. An administration set is also shown in Figure 7. Similarly, the embodiments of Figures 66, 70, 74, 78, 82, 84, 86 and 88 each include an administration set, although the administration sets of these Figures are not specifically referred to by a reference number. The effluent fluid line 530 may be standard PVC tubing or other material known to those skilled in the art.

Appl. No. : 09/892,900
Filed : June 26, 2001

Please amend the paragraph beginning at page 56, line 14 as follows:

B25 For many applications of the present invention, the fluid container 500 preferably contains 50 cc of a fluid 550. Although these volumes are preferred in the present invention, other sizes of fluid containers may be easily constructed using the disclosure of the present invention. These varying size fluid containers are contemplated by this disclosure.

Please amend the Abstract of the Disclosure as follows:

Abstract of the Disclosure

B26 10-15-03 Disclosed is an An infusion pump for expelling a fluid from a collapsible fluid reservoir to a patient. The pump ~~comprises~~ includes a housing having a chamber therein for receiving the fluid reservoir. A first wall is provided on the housing for contacting the fluid reservoir, and a second wall is movable from a first position distanced from the first wall to form the chamber therebetween, and a second position relatively closer to the first wall. Advancing the movable wall from the first position to the second position expels fluid from the collapsible reservoir at a substantially constant rate by applying increasing force on the fluid reservoir through the dispensation cycle. Preferably, the first and second walls are provided with non-planar complementary surface configurations for contacting the collapsible reservoir. Retraction mechanisms for retracting the movable wall from the second position to the first position, and user readable indicium of the status of the dispensation cycle are also disclosed.